COALITION OF

Wound Care Manufacturers

August 30, 2011

Donald Berwick, MD
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-1577-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Sent Electronically

Re: **Comments on CMS-1577-P:** Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment ("Proposed Rule")

Dear Dr. Berwick:

The Coalition of Wound Care Manufacturers (the "Coalition") appreciates the opportunity to submit comments to the proposed changes to the definition of durable medical equipment ("DME") published by the Centers for Medicare & Medicaid Services ("CMS" or the "Agency") in the July 8, 2011 Federal Register (76 Fed. Reg.40498). The Coalition represents leading manufacturers of surgical dressings and other medical devices and supplies used by Medicare beneficiaries for the treatment of wounds, including skin substitutes

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The Coalition has signed on to the Alliance of HCPCS II Coding Reform comments and is in agreement with its principles. This issue is very important to our members and therefore we wanted to submit our own comments underscoring the salient concerns and recommendations which we have identified below.

Our comments are specifically focused on the 3 year minimum lifetime requirement. We believe that the three year requirement is inappropriate and arbitrary. Our concern is that by setting an arbitrary 3-year expected life in the regulatory definition of DME, CMS may have the unintended consequence of stifling innovation that could lead to improved care for Medicare beneficiaries and reduced costs for the Medicare program.

Instead of a three year minimum lifetime, the Coalition recommends that the minimum lifetime should be aligned with a product's intended clinical use. A product may be durable and able to withstand repeated use by a single beneficiary, yet may not be

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appropriate for repeated use by multiple beneficiaries due to hygiene concerns or because the item is customized for a single person and only be typically required for a period of less than 3 years. Why would this type of technology be required to meet such an artificial lifetime criterion? This requirement has the potential of increasing costs to manufacturers without providing any meaningful value to Medicare beneficiaries. For instance, in negative pressure wound therapy (NPWT), the Medicare LCD clearly limits the maximum NPWT benefit to four months. Based upon the four month coverage limitation for NPWT beneficiaries applying a 3 year minimum lifetime requirement would be unduly restrictive to the development of durable products which need only be designed to support the needs of a specific single beneficiary. Furthermore, in clinical practice, beneficiaries receiving NPWT routinely do not exceed two months of therapy which only further reduces the true durability requirement need for this therapy.

Moreover, the Coalition requests that CMS should provide clear guidance as to the prospective applicability and scope of the proposed rule. CMS indicates that the additional requirement of a 3 year minimum lifetime criterion would be applied prospectively, the proposed rule would not impact items classified and covered as DME before the new rule takes effect or supplies and accessories used with covered DME? Does this mean items currently being billed to Medicare using existing HCPCS codes, items currently code verified under existing HCPCS codes, or any item that would fit into an existing product category? How would CMS handle items currently billed using miscellaneous codes such as, K0108 or E1399? It is not clear whether any item requiring a new HCPCS code would be subject to this added requirement even if it would compete with items already classified as DME. It also isn't clear whether the new requirement would apply in cases where existing HCPCS codes are split into 2 or more HCPCS codes.

In addition, by grandfathering only those items classified as DME prior to the effective date of the final rule, the proposed rule would create disparate requirements for similar products categorized according to the same HCPCS code and reimbursed at the same amount by CMS. The net effect of the new 3 year expected life requirement would be to increase costs to all future DME items as manufacturers seek to demonstrate a 3 year expected life, while items classified as DME prior to the rule would perform the same function for the same price and will not be required to make a similar showing. The irregular application of the requirement to items identified by the same HCPCS code will stifle innovation that could have resulted in new products that deliver better care at a lower cost to the Medicare program.

If it is the intent of CMS not to stifle innovation, as well as to save money for the Medicare program, a rigid durability requirement, such as the one proposed, is not advisable.

The Coalition will be requesting a meeting with the agency after the comment period has closed to collaborate and further develop a clear definition of "durable" that would be appropriate for various product categories and that promotes innovation. We look

forward to working with you on this very critical issue that could impact innovation for years to come.

Sincerely,

Marcia Nusgart, R.Ph

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